Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effectiveness of inhalation aromatherapy with lavender essential oil versus placebo on anxiety in endoscopic Candidate Patients

Protocol summary

Study aim

Determining the effect of lavender aromatherapy versus placebo on the anxiety of upper gastrointestinal endoscopy candidates

Design

A clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, involving 90 patients, for which the block randomization method is used, in which we randomly use one of the six permutations of two out of four for group assignment

Settings and conduct

A study in the field of reducing anxiety is carried out in the endoscopy department of Vasai Hospital. At first, Spielberger's anxiety and demographic questionnaires are completed by the patients. In the intervention group, patients inhale lavender oil-soaked gas for 20 minutes. In the placebo group, grape seed oil is inhaled. After completing that, the Spielberger questionnaire is completed again. In order to blind the study, the patients and clinical caregivers do not know what intervention each patient receives.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Being able to read and write, not having an allergy to lavender or cosmetics, not having a history of plant allergies and lung disease, not having a problem with smell, age between 18 and 65 years, voluntary participation in the study, not having anxiety disorders or psychological illness .exclusion criteria : Willingness to refrain from studying at any stage of intervention, need for urgent endoscopy, severe pain during research

Intervention groups

In the intervention group, gauze impregnated with three drops of lavender oil is attached to the patient's neck within a radius of 20 cm from the patient's nose, and the patients inhale it for 20 minutes. And in the placebo group, patients will inhale grape seed oil in the same way for twenty minutes.

Main outcome variables

Finding an practical intervention with less complications in order to reduce anxiety in the bedside

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230729058960N1**
Registration date: **2023-09-29, 1402/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-29, 1402/07/07**
Update count: **0**

Registration date

2023-09-29, 1402/07/07

Registrant information

Name

Elahe Garousi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3365 0087

Email address

garousie98@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of inhalation aromatherapy with lavender essential oil versus placebo on anxiety in endoscopic Candidate Patients

Public title
Investigating the effect of lavender on reducing endoscopic anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being literate in reading and writing Not having an allergy to lavender or perfume and cosmetics No history of herbal allergy Not having asthma and lung disease Not having a smell problem Age between 18 and 65 years Not having anxiety disorders or psychological illness Voluntary participation in the study

Exclusion criteria:
Intention to withdraw from the study at any stage of the intervention The need for urgent endoscopy Severe pain during research

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the study, participants in the control group are told that they are inhaling lavender oil, while in fact they are inhaling grape seed oil as a placebo. In addition, clinical supervisors and outcome assessors are unaware of which participant is receiving which oil

Placebo
Used

Assignment
Parallel

Other design features
Block randomization is such that for every four candidates who enter the study, according to the permutation of 2 out of 4, there are six possible ways that two people out of four are selected for the intervention group. We write these six cases and randomly choose one of them and according to that we assign the candidates to the two intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Shohadaye Hastei Blvd

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2023-05-26, 1402/03/05

Ethics committee reference number
IR.MEDSAB.REC.1402.055

Health conditions studied

1

Description of health condition studied
anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
anxiety

Timepoint
Immediately after the end of twenty minutes of aromatherapy

Method of measurement
Speilberger Anxiety Inventory

2

Description
Age

Timepoint
Before intervention

Method of measurement
Demographic questionnaire

3

Description
gender

Timepoint
Before intervention
Method of measurement
Demographic questionnaire

4

Description
Level of education
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

5

Description
marital status
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

6

Description
Employment status
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

7

Description
The economic situation
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

8

Description
Previous history of endoscopy
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

9

Description
Insurance
Timepoint
Before intervention
Method of measurement
Demographic questionnaire

10

Description
group
Timepoint
Before intervention
Method of measurement
After permuted block randomization

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohammad Vasei Sabzevar Hospital
Full name of responsible person
Ali Mohammad Abadi
Street address
Vasei Hospital, Tohid Shahr Blvd. Sabzevar city
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Fax
+98 51 4465 3861
Email
waseehospital@medsab.ac.ir
Web page address
https://www.medsab.ac.ir/index.aspx?pageid=11067

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Kazem Hasanpour
Street address
Deputy of research and technology, Sabzevar University of Medical Sciences campus, Above the

Memorial of Unknown Martyrs, Nuclear Martyrs Blvd., Sābzevar City

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Email
vc.Research@medsab.ac.ir

Web page address
http://vcresearch.medsab.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sabzevar University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Elahe Garousi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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No 39 , 5th dead end , Sadi St, ,Sadi Ave .Qazvin Town,

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information of people participating in the research The results of the statistical surveys conducted on the research participants Research protocol Ethical considerations and codes The informed consent form used in the research

When the data will become available and for how long

Six months after the results are published, applicants can apply for documents.

To whom data/document is available

Researchers working in academic institutions and university faculty members can apply for documents.

Under which criteria data/document could be used

In order to use the documentation in other researches, it is necessary to refer to the present research.

From where data/document is obtainable

Six months after the results are published, applicants can send a message to the following email to receive documents that can be shared, and the documents will be sent to them within a maximum of one week. garousiE9@medsab.ac.ir

What processes are involved for a request to access data/document

Six months after the results are published, applicants can send a message to the following email to receive documents that can be shared, and the documents will be sent to them within a maximum of one week. elahe.gar0030@gmail.com

Comments